REMARKS

Claims 1 and 3-17 are pending. The amendment to claim 1 and claims 14-15 find support in the specification at page 3, lines 31-42. Claims 16-17 find support at page 5, lines 21-24.

Claims 1-3, 9, 10 and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Krape et al. (WO 99/00131). Applicants respectfully traverse this rejection. Applicants disagree that the 4% and 14% volatile organic solvent of Krape et al.'s examples 5 and 6 meet the present claim limitation that the preparation be substantially free of volatile organic solvent. In any event, applicants have amended claim 1 to clarify the preparation is free of volatile organic solvent to at least the extent that would result if the preparation were produced by a melt process. It is clear that, if a volatile organic solvent is present during the production of the claimed preparation, most if not all of the solvent will be removed during said production, provided that a melt process is used. This is because processing the pharmaceutically acceptable matrix material (which comprises a completely synthetic polymer having a glass transition temperature of >90°C in the anhydrous state) requires processing temperatures well above the boiling point of volatile organic solvents such as methanol and ethanol. Therefore, Krape et al. does not anticipate the present claims.

Claims 1 and 9-13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Miranda et al. (US 5,656,286). In the Advisory action of February 8, 2005, the Examiner seems to reject previous claim 2 as well. Applicants respectfully traverse this rejection. Applicants urge that paroxetine and paroxetine hydrochloride differ significantly from each other. In particular, paroxetine is an oil (WO 99/00131, page 1, lines 19-23),

whereas paroxetine hydrochloride is a solid that shows a tendency to polymorphism (cf. present application, page 1, lines 20-21). According to Miranda et al., however, the presence of crystals in transdermal drug delivery systems is generally undesirable, and if the drug is present in crystalline form, it is not available for release from the system and therefore not available for delivery (Miranda et al., column 2, lines 4-10). Thus, Miranda et al. would not have suggested to a person having ordinary skill in the art using paroxetine hydrochloride instead of paroxetine.

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COMPLETE LISTING OF AMENDED CLAIMS

1. (currently amended) A solid or semisolid preparation ~~which is substantially free of volatile organic solvent~~, said preparation comprising paroxetine hydrochloride in the form of a molecular dispersion in a pharmaceutically acceptable matrix material which comprises a completely synthetic polymer having a glass transition temperature of >90°C in the anhydrous state, and wherein said preparation is substantially free of volatile organic solvent to at least the extent that would result if the preparation were produced by a melt process wherein the melt comprises paroxetine or one of its salts and the matrix material.

2. (canceled)

3. (previously presented) The preparation of claim 1 having an active ingredient release of at least 80% after 30 min.

4. (currently amended) A process for producing a solid or semisolid preparation which is substantially free of volatile organic solvent, said preparation comprising paroxetine or one of its physiologically acceptable salts in the form of a molecular dispersion in a pharmaceutically acceptable matrix material which comprises a completely synthetic polymer having a glass transition temperature of >90°C in the anhydrous state,

which process comprises the paroxetine or one of its salts and the matrix material being mixed to give a homogeneous melt in an extruder and subsequently being shaped.

5. (previous presented) The process of claim 4 for producing a paroxetine hydrochloride preparation, wherein paroxetine is processed with ammonium chloride and the matrix materials to give a homogeneous melt.

6. (previously presented) The process of claim 5, wherein amorphous paroxetine or one of its physiologically acceptable salts is employed.

7. (previously presented) The process of claim 4, wherein the melt is produced at a temperature in the range of 80 to 150°C.

8. (previously presented) The process of claim 4, further comprising applying a vacuum to the extruder while the paroxetine or one of its salts and the matrix material are being mixed if solvents are present therein.

9. (previously presented) The preparation of claim 1, which is also free of water.

10. (previously presented) The preparation of claim 1, wherein the polymer has a glass transition temperature of >90°C to 110°C in the anhydrous state.

11. (previously presented) The preparation of claim 1, wherein the polymer is a copolymer of N-vinylpyrrolidone and vinyl acetate.

12. (previously presented) The preparation of claim 11, wherein the polymer is copovidone.

13. (previously presented) The preparation of claim 1, which is a solid.

14. (new) The preparation of claim 1, wherein said preparation is substantially free of volatile organic solvent to at least the extent that would result if the preparation were produced by a melt process at temperatures in the range of from 80 to 150°C.

15. (new) The preparation of claim 1, wherein said preparation is substantially free of volatile organic solvent to at least the extent that would result if the preparation were produced by a melt process and a vacuum applied during such process.

16. (new) The preparation of claim 1, wherein the preparation is in the form of granules.

17. (new) A tablet or capsule comprising the preparation of claim 1.